PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/569,958	Group Art Unit:	3768
Filing Date:	November 3, 2006	Examiner:	Hien Ngoc Nguyen
Applicant:	Kristine FUIMAONO et al.		
Title:	METHOD AND DEVICE FOR VISUALLY SUPPORTING AN ELECTROPHYSIOLOGY CATHETER APPLICATION IN THE HEART		
Attorney Docket:	32860-001018/US		

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APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 41.37

In accordance with the provisions of 37 C.F.R. § 41.37, Appellants submit the following Appeal Brief.

I. 37 C.F.R. § 41.37(c)(1)(i) – REAL PARTY IN INTEREST

The real party in interest for the present application is SIEMENS AKTIENGESELLSCHAFT. An assignment of the rights associated with the present application was recorded with the United States Patent and Trademark Office on November 03, 2006 on reel/frame no. 018504/0041.

II. 37 C.F.R. § 41.37(c)(1)(ii) – RELATED APPEALS AND INTERFERENCES

There are no known appeals, interferences, or judicial proceedings that will directly affect, be directly affected by, or have a bearing on the Board's decision in this Appeal.

III. 37 C.F.R. § 41.37(c)(1)(iii) – STATUS OF CLAIMS

Claims 1-26 are pending in the present application, with claims 1, 12, 19 and 22 being the independent claims. Claims 1-26 stand rejected.

Claims 1-3, 5, 8-9, 12, 14 and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,556,695 to Packer ("Packer") and in view of US 2002/0176608 to Rose ("Rose").

Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of "A System for Multimodality Image Fusion" to Hemler *et al.* ("Hemler") and further in view of DE 19953308 to Williams *et al.* ("Williams").

Claims 13, 18 and 25-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose, further in view of Hemler and Williams.

Claims 10-11 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of US 2003/0018251 to Solomon et al. ("Solomon").

Claims 15-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of Solomon.

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of US 2002/0087329 to Massaro ("Massaro").

Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose, in view of US 6,572,476 to Shoji et al. ("Shoji") and further in view of US 2004/0233217 to Chiu et al. ("Chiu").

Claims 1-26 are being appealed.

IV. 37 C.F.R. § 41.37(c)(1)(iv) – STATUS OF AMENDMENTS

No amendments were filed subsequent to the August 9, 2010 Final Office Action.

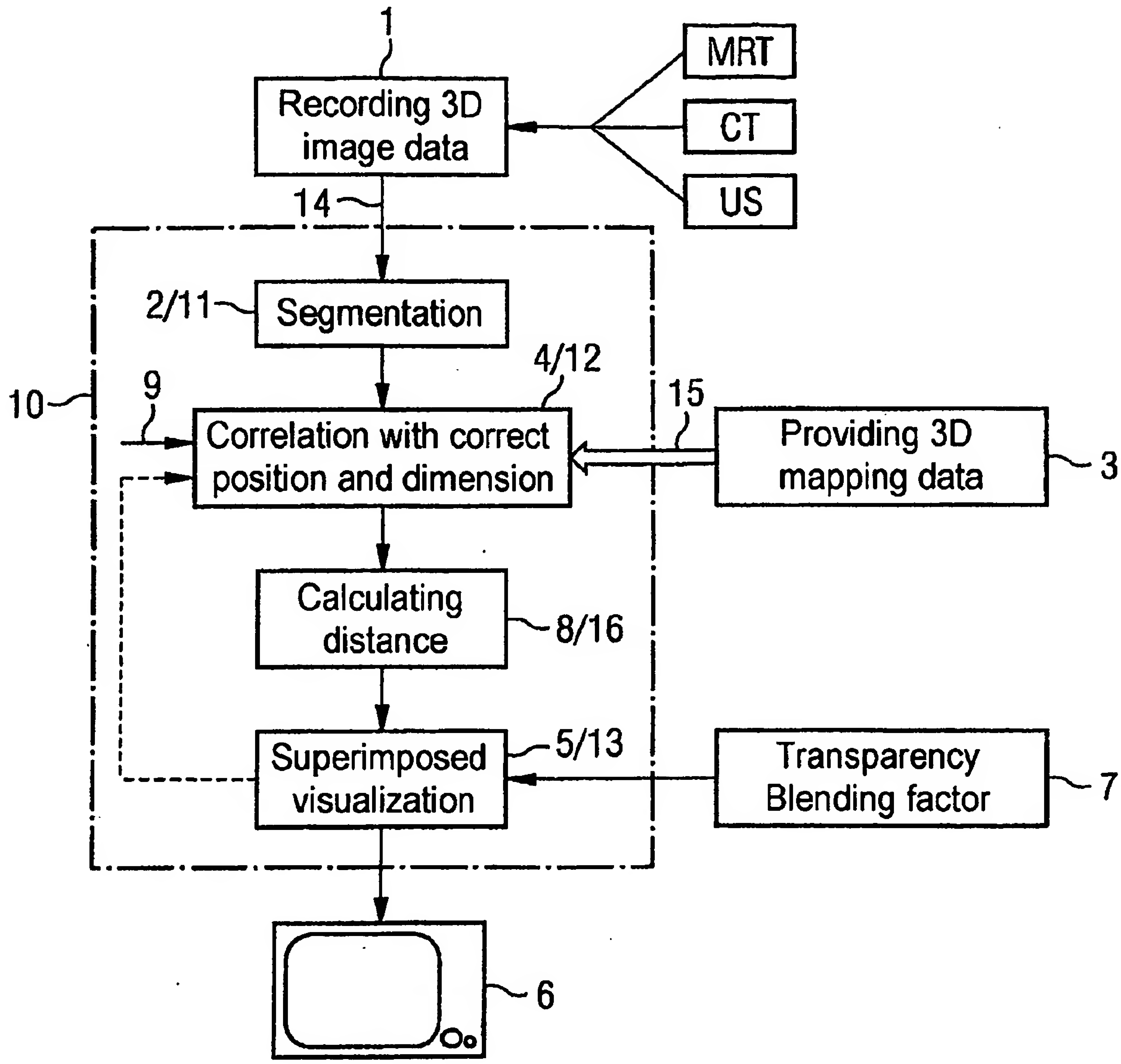
V. 37 C.F.R. § 41.37(c)(1)(v) – SUMMARY OF CLAIMED SUBJECT MATTER

Introduction

The following explains the subject matter set forth in each claim argued on appeal and each independent claim by way of example embodiments in the specification by page and line number, and in the drawings, if any, by reference characters only to satisfy 37 C.F.R. § 41.37(c)(1)(v). This concise explanation relies on example embodiments from the specification to describe the claims; however, the claims recite subject matter not limited to these example embodiments.

FIG. 1 illustrates the individual steps in the performance of the present method and individual modules of the associated device, according to a non-limiting embodiment of the present invention. FIG. 1 has been reproduced below for convenience of reference.

According to example embodiments, in a first step 1, the 3D image data of the area to be treated, particularly of the heart chamber to be treated, are recorded. The 3D image data are recorded by way of a method of tomographic 3D imaging such as, for example, X-ray computer tomography, magnetic resonance tomography or 3D ultrasonic techniques. During the recording of the 3D image data, the image data are in each case recorded for the same heart phase for which the electroanatomical 3D mapping data will also be provided later. This is ensured by ECG gating of the image recording and recording of the 3D mapping data, for example by referring to a percentage of the RR interval or to a fixed time interval before or after the R peak.



According to example embodiments, it is of importance to record high-resolution image data of the heart chamber which is electroanatomically measured during the catheter application. Preferably, a contrast medium in association with a test bolus or bolus tracking is therefore used for recording the 3D image data.

According to example embodiments, in a second step, the segmentation 2 of the 3D image data for extracting the 3D surface profile of vessels and heart chambers contained therein takes place. The segmentation may represent the

surface profile of objects in the superimposed image representation and may be used for the correlation with the 3D mapping data in the correct position and dimension.

According to example embodiments, segmentation takes place in the segmentation module 11 of the present device 10. This segmentation module 11 receives the recorded 3D image data via a corresponding input interface 14. In the same way, the 3D mapping data are supplied to the device 10 via the same or another interface 15, as a rule continuously, during the period of the electrophysiological catheter application.

According to example embodiments, segmentation of the heart chamber to be treated can take place in the form of a 2D segmentation in individual layers. One possibility resides in performing a fully automatic segmentation of all layers of the heart chamber obtained by the imaging method. As an alternative, one or more of the layers can also be segmented interactively by an operator and the layers following in each case can be segmented automatically on the basis of the prior knowledge of the layers already segmented. After the segmentation of all individual layers, the 3D surface profile of the heart chamber can then be reconstructed.

According to example embodiments, segmentation can also take place as 3D segmentation of the heart chamber to be treated using 3D segmentation techniques. The 3D surface profile of the objects, obtained from the segmentation, is supplied to the registration module 12 in which the 3D image data or, respectively, the data of the 3D surface profile obtained from these, are correlated with the 3D mapping data provided in step 3 in the correct position and dimension. The 3D mapping data are obtained via a mapping catheter which supplies 3D coordinates of surface points of the heart chamber to be treated via a 6D position sensor integrated into the tip of the catheter.

According to example embodiments, in the registration step 4 in the registration module 12, the dimensions of the 3D image data and of the 3D mapping data are also matched apart from the correlation in the correct position. This is required in order to achieve the most accurate superimposition possible of the 3D image data of the heart chamber or of its surface in the same position, orientation, scaling and shape with the corresponding visualization of the heart chamber from the 3D mapping data.

According to example embodiments, the registration can take place by visual matching. For this purpose, an operator changes the data visualized until the position, orientation, scaling and/or shape of the heart chamber displayed matches in both representations, i.e. on the basis of the 3D image data and on the basis of the 3D mapping data. The visual matching can take place via a suitable graphical user interface 9. Artificial markers can be used for the registration.

According to example embodiments, global anatomic markers may be used. These distinct points must be identifiable in the 3D image data and are preferably approached with the mapping catheter by using a fluoroscopic imaging technique. The distinct points can then be detected automatically in the 3D image data and the 3D mapping data so that a correlation of these data with the correct position and dimension can be calculated.

INDEPENDENT CLAIM 1

Independent claim 1 recites "visualizing electroanatomical 3D mapping data, provided during the performance of the catheter application, of an area of the heart to be treated." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0032-0034] of the original specification.

Independent claim 1 additionally recites "recording 3D image data of the area to be treated with a method of tomographical 3D imaging before the catheter application is carried out." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0024] of the original specification.

Independent claim 1 also recites "extracting a 3D surface profile of objects in the area to be treated from the 3D image data by segmentation." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0031-0033] of the original specification.

Independent claim 1 also recites "visualizing the electroanatomical 3D mapping data and 3D image data representing at least the 3D surface profile, the visualized electroanatomical 3D mapping data and 3D image data representing at least the 3D surface profile being registered, with correct position and dimension, by automatically correlating the electroanatomical 3D mapping data and 3D image data representing the 3D surface profile by surface matching, in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0031-0035], of the original specification.

INDEPENDENT CLAIM 12

Independent claim 12 recites "at least one input interface for electro-anatomical 3D mapping data and 3D image data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0034] and FIG. 1 of the original specification and drawings.

Independent claim 12 recites "a segmentation module constructed for segmenting the 3D image data in order to extract a 3D surface profile of objects

contained within a volume recorded by way of the 3D image data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0026] and FIG. 1 of the original specification and drawings.

Independent claim 12 recites "a registration module connected to the segmentation module, the registration module configured to automatically correlate the electroanatomical 3D mapping data and the 3D image data representing the 3D surface profile by surface matching of the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data in at least one stage of the registration, the registration being carried out with correct position and dimension." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0031-0035] and FIG. 1 of the original specification and drawings.

Independent claim 12 recites "a visualization module connected to the registration module, to superimpose the 3D mapping data and at least the 3D image data representing the 3D surface profile on one another in the correct position with the correct dimension and provide these for visualization via a display device." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0049-0050] and FIG. 1 of the original specification and drawings.

INDEPENDENT CLAIM 19

Independent claim 19 recites "recording 3D image data of an area of the heart to be treated with a method of tomographical 3D imaging, before electroanatomical 3D mapping data is provided during the performance of the catheter application." This reads on the non-limiting example embodiment

disclosed, for instance, in paragraph [0024] and FIG. 1 of the original specification and drawings.

Independent claim 19 recites "extracting a 3D surface profile of objects in the area to be treated from the 3D image data by segmentation." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0031-0033] and FIG. 1 of the original specification and drawings.

Independent claim 19 recites "registering, with correct position and dimension, by automatically correlating the electroanatomical 3D mapping data and 3D image data representing the 3D surface profile by surface matching, in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0026, 0032, 0035 and 0038-0039] and FIG. 1 of the original specification and drawings.

Independent claim 19 recites "displaying 3D mapping data and the 3D image data representing the 3D surface profile superimposed on one another in correct dimension and position." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0049-0050] and FIG. 1 of the original specification and drawings.

<u>Independent Claim 22</u>

Independent claim 22 recites "means for recording 3D image data of an area of the heart to be treated with a method of tomographical 3D imaging, before electroanatomical 3D mapping data is provided during the performance of the catheter application." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0024] and FIG. 1 of the original specification and drawings.

Independent claim 22 recites "means for extracting a 3D surface profile of objects in the area to be treated from the 3D image data by segmentation." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0031-0033] and FIG. 1 of the original specification and drawings.

Independent claim 22 recites "means for displaying the electroanatomical 3D mapping data and 3D image data representing at least the 3D surface profile superimposed on one another." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0049-0050] and FIG. 1 of the original specification and drawings.

Independent claim 22 recites "the electroanatomical 3D mapping data and 3D image data representing the 3D surface profile being registered by a registration means, with correct position and dimension, and by automatically correlating, by surface matching in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0026, 0032, 0035 and 0038-0039] and FIG. 1 of the original specification and drawings.

VI. 37 C.F.R. § 41.37(c)(1)(vi) – GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Appellants seek the Board's review of the rejection of claims 1-3, 5, 8-9, 12, 14 and 19-24 under 35 U.S.C. § 103(a) as being unpatentable over US 6,556,695 to Packer ("Packer") and in view of US 2002/0176608 to Rose ("Rose").

B. Appellants seek the Board's review of the rejection of claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of "A System for Multimodality Image Fusion" to Hemler *et al.* ("Hemler") and further in view of DE 19953308 to Williams *et al.* ("Williams").

C. Appellants seek the Board's review of the rejection of claims 13, 18 and 25-26 under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose, further in view of Hemler and Williams.

D. Appellants seek the Board's review of the rejection of claims 10-11 and 17 under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of US 2003/0018251 to Solomon et al. ("Solomon").

E. Appellants seek the Board's review of the rejection of claims 15-16 under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of Solomon.

F. Appellants seek the Board's review of the rejection of claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of US 2002/0087329 to Massaro ("Massaro").

G. Appellants seek the Board's review of the rejection of claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose, in view of US 6,572,476 to Shoji et al. ("Shoji") and further in view of US 2004/0233217 to Chiu et al. ("Chiu").

VII. <u>37 C.F.R. § 41.37(c)(1)(vii) – ARGUMENT</u>

A. <u>Rejection of Claims 1-3, 5, 8-9, and 19-24 under 35 U.S.C. § 103(a) is Erroneous</u>

The Examiner takes the position that claims 1-3, 5, 8-9 and 19-24 are unpatentable over US 6,556,695 to Packer ("Packer") and in view of US 2002/0176608 to Rose ("Rose"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

<u>Principles of Law</u>

In order to set forth a prima facie case of obviousness under 35 U.S.C. § 103(a), the Examiner must make the factual determinations set forth in <u>Graham v. John Deere Co.</u>, 282 U.S. 1, 17 (1966), including identifying differences between the claimed invention and the prior art. Each limitation of a claim must be given weight in this determination in order to determine whether the "subject matter as a whole would have been obvious." 35 U.S.C. § 103(a). In combining references and accounting for differences between a claim and the applied art, the Examiner must provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." <u>KSR Int'l Co. v. Teleflex, Inc.</u>, 127 S.Ct. 1727, 1741 (2007). The Board of Patent Appeals and Interferences has plenary review of issues of obviousness and the teachings of the applied references underlying the appealed rejections. 35 U.S.C. § 6(b).

<u>PACKER FAILS TO DISCLOSE OR FAIRLY SUGGEST ALL CLAIMED LIMITATIONS</u>

It is alleged in the Office Action that FIG. 1, col. 2, lines 14-60, col. 11, lines 33-48 and col. 12, lines 28-61 of Packer teach "visualizing electroanatomical 3D

mapping data, provided during the performance of the catheter application, of an area of the heart to be treated," as recited in independent claim 1.

However, the Appellants submit that Packer fails to disclose or even suggest any "electroanatomical 3D mapping data," as required by claim 1. Fig. 1 of Packer merely illustrates a MRI apparatus. Col. 3, lines 51-67 of Packer relate to the imaging modality for producing the high resolution model (CT, MRI, ultrasound). Col. 2, lines 14 -60 of Packer disclose acquiring image data of the subject anatomy and reconstructing an image which is a high resolution model of the subject anatomy; performing a medical procedure in which the subject anatomy is imaged in real-time by acquiring low resolution images at a high frame rate; registering the high resolution model of the subject anatomy with each acquired low resolution image; and displaying images of the registered high resolution model of the anatomy. As is understood, the cited sections of Packer relate to a process of rendering 3D surfaces on a 2D display and this all mapping data is two dimensional. Accordingly, Packer fails to disclose or even suggest any "3D mapping data," as recited in independent claim 1.

It is further alleged in the Office Action at Page 4 that col. 5, line 63-col. 6, line 48 of Packer disclose "extracting a **3D surface profile** of objects in the area to be treated from the 3D image data by segmentation," as recited in independent claim 1. (Emphasis Added)

As discussed above, the cited sections of Packer are directed to the process of rendering acquired 3D surfaces on a 2D display. Further, these sections of Packer are directed to processing the acquired 3D image data into a 4D model from which 3D heart wall surfaces can be rendered. This process of rendering acquired 3D surfaces involves segmenting of the heart walls and tiling of the surfaces of the segmented heart wall images. However, no "3D surface profile" is ever extracted.

Packer fails to teach or even suggest "extracting a 3D surface profile," as recited in independent claim 1.

The Examiner admits that Packer does not explicitly teach "3D surface profile," as required by claim 1, and relies on the teachings of Rose to overcome the noted deficiencies of Packer.

Particularly, the Examiner alleges that paragraphs **[0005-0007]** of Rose teach "extracting a 3D surface profile," as recited in independent claim 1. Appellants disagree.

THE COMBINATION OF PACKER AND ROSE IS IMPROPER

Rose is directed to a non-contact surface profiling method using light. Rose focuses primarily upon road surfaces. However, as per Rose, the discussion applies equally to any surface intended for vehicular traffic. According to Rose, these surfaces include, but are not limited to, highways, roads, ramps, parking, and service areas for ground vehicles (trucks, cars, busses, etc.), runways, taxiways, parking aprons, and hangar floors for aircraft, and tracks and roadbeds for railroads. The terms "road" and "road surface," as used herein, refer specifically to "a road" and "a surface of a road," respectively, and refer generally to "a way or course for ground, air, or rail vehicles" and "a surface of a way or course," respectively. The sections of Rose cited by the Examiner are reproduced below.

> **[0005]** In the industry, road condition is measured by profiling. Profiling is the obtaining of a profile or series of profiles of the road surface. A profile is substantially a cross-sectional view of the surface of the road. A profile depicts the contours of the road, thereby demonstrating the form, wear, and irregularities of the road surface.
>
> **[0006]** A transverse profile is a cross-sectional view of the road surface or a portion thereof taken substantially perpendicular to the direction of travel. A transverse profile may be used to depict rutting,

> potholes, scaling, chipping, and edge damage of the road surface over time.
>
> **[0007]** A longitudinal profile is a cross-sectional view taken substantially in the direction of travel. A longitudinal profile may be used to depict the grade, waviness, and roughness of the road surface. Longitudinal profiles may be used to monitor the wear of the road surface over time to facilitate maintenance planning.
>
> (Emphasis Added)

Absolutely nowhere in Rose is it mentioned that the techniques disclosed therein can be used in the field of medical imaging. Thus, nowhere in Rose is it disclosed that the device disclosed therein can be modified to image living organisms, or, rather, "extract 3D surface profiles of objects in an area to be treated," as claimed. Accordingly, although Rose is directed to an imaging method, Rose is not directed to any medical imaging method that "[extracts] 3D surface profiles of objects in an area to be treated," as claimed. On the other hand, Packer is directed to a completely different technological field of medical imaging. Applicants submit that it would not be obvious for one of ordinary skill in the art dealing with electroanatomical mapping or endocardial ablation to rely on Rose that deals with two-dimensional surface profiling of roads.

Appellants submit that the combination of Packer and Rose is not obvious and is based on improper hindsight reconstruction gleaned from viewing Applicants' Specification and reading the claims, and not on a reason with some rational underpinnings for combining Packer and Rose. Rose does not appear to be interested in the 3D surface profiling of organs of living organisms. The Examiner has provided no evidence or reasoning that Rose appears to be interested in producing 3D surface profiles of organs of living organisms.

Accordingly, the combination of Packer and Rose is not an obvious combination of prior art elements or a simple substitution of one known element

for another, leading to predictable results, or any other indicator of potential obviousness. Rather the extensive amount of modification needed is suggested nowhere in the cited references or by the Examiner, and is born from use of impermissible hindsight reconstruction in view of the Appellants' Specification and reading of the claims. (See, for example, *Ex parte* Kobayashi, Appeal 2009-000884, Application 10/031,282).

Applicants submit that for all the above reasons, the alleged combination of Packer and Rose is improper and, even if combined (which is not admitted), the combination fails to render the limitation of independent claim 1, and the somewhat similar features recited in independent claims 12, 19 and 22 obvious to one of ordinary skills in the art.

ROSE FAILS TO REMEDY THE DEFICIENCIES OF PACKER

As discussed above, Rose is directed to a non-contact surface profiling method using light. Rose fails to teach, suggest or even point out any "**visualizing electroanatomical 3D mapping data**, provided during the performance of the catheter application, of an area of the heart to be treated; **recording 3D image data of the area to be treated with a method of tomographical 3D imaging** before the catheter application is carried out; [and] **visualizing the electroanatomical 3D mapping data and 3D image data representing at least the 3D surface profile**," as recited in independent claim 1, and the somewhat similar features recited in independent claims 12, 19 and 22. (Emphases Added)

Rose is directed to primarily road surfaces and to any surface intended for vehicular traffic. Rose does not utilize any methods of tomographical 3D imaging. The system 20 in FIG. 1 of Rose is a vehicular-mounted system. The components of system 20 are mounted upon and/or inside of a vehicle 40. The type of vehicle to

be used for vehicle 40 is not relevant to the present invention, and a wide assortment of vehicles, from hand carts, though golf carts, cars, trucks, railroad cars, and even aircraft may be used. Further, the device and method of Rose incorporates projecting a <u>two-dimensional pattern</u> of alternating relatively lighter and relatively darker regions upon a surface that is profiled. Rose fails to teach or fairly suggest any "**electroanatomical 3D mapping data**," "**3D image data**" and/or "**3D surface profile**," as recited in independent claim 1.

Still further, Rose does not even appear to be interested in performing any of the above claimed features on any of the vehicular surfaces that the Rose device and method profiles. Accordingly, Rose fails to remedy the above discussed deficiencies of Packer and a combination of the teachings of Packer and Rose (of combinable, which is not admitted) would still not render the limitations of claims 1, 19 and 22 obvious to one of ordinary skill in the art.

With respect to dependent claims 2-11, 17, 20-21 and 23-24, Applicants submit that claims 2-11, 17, 20-21 and 23-24 are dependent directly or indirectly on independent claims 1, 19 and 22, and independent claims 1, 19 and 22 are shown to be patentable at least for the reasons given above. Claims 2-11, 17, 20-21 and 23-24 are also patentable at least by virtue of their dependency from claims 1, 19 and 22.

Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

B. <u>Rejection of Claims 12 and 14 under 35 U.S.C. § 103(a) is Erroneous</u>

The Examiner takes the position that claims 12 and 14 are unpatentable over US 6,556,695 to Packer ("Packer") and in view of US 2002/0176608 to Rose

("Rose"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

With respect to independent claim 12, the Examiner alleges that Packer teaches "a registration module connected to the segmentation module, the registration module configured to **automatically correlate** the electroanatomical 3D mapping data and the 3D image data representing the 3D surface profile by surface matching of the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data in at least one stage of the registration, the registration being carried out with correct position and dimension," in FIG. 1, FIG. 8, col. 2, lines 14-60 and col. 9, line 21 - col. 10, line 36.

Fig. 8 shows a flowchart for producing a high resolution, large field of view images in real-time on the display, "overlaying devices on image (242)" and an arrow from block 242 to the beginning. Col. 9, line 21 – col. 10, line 36, describes the flowchart (FIG. 8), <u>without</u> referring to *any* electrophysiological data. The cited text passages or figures do not describe how electrophysiological data are merged with the anatomic model, especially fail to disclose or even suggest any "automatically [correlation of] the electroanatomical 3D mapping data and the 3D image data representing the 3D surface profile by surface matching of the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data in at least one stage of the registration, the automatic correlation carried out with correct position and dimension," as recited in independent claim 12.

Packer in col. 12, line 35 – col. 13, line 15 discloses that the location of the electrodes is registered <u>manually</u> with the high resolution image. Without this manual registration, it would not be possible to assign the measured activation in form of a color modulation of the appropriate pixel. Accordingly, Packer fails to teach or fairly suggest any "automatic correlation." Further, sensing electrical

signals in Packer is not "3D mapping" as claimed, since the electrical signals produced by the electrodes of Packer (268, FIGS. 9-10) indicate the relative timing of the signals during cardiac cycle. As such, they cannot be regarded as electroanatomical 3D mapping data, but only as voltage over time signals.

Additionally, the arrow from block 242 to the beginning (Fig. 8) does not mean that the high resolution model with the overlayed electrophysiological data is input to the registration procedure with the real-time image. The Examiner alleges that the high resolution image of Packer would contain the electrical activation map and the registration in block 236 could be regarded as registration of the mapping data with the real-time image. However, the arrow means that the displayed image is continuously updated, i.e. a new real-time image is registered with a newly selected high resolution image (according to the ECG phase) and this image is overlayed again with the electrophysiological data by modulation the pixel color. Therefore, Packer does not disclose an "automatic registration" of the 3D image data and electroanatomical 3D mapping data.

For the reasons given above, Applicant submits that Rose fails to remedy the deficiencies of Packer, since Rose fails to teach or fairly suggest any "registration module configured to **automatically correlate** the electroanatomical 3D mapping data and the 3D image data representing the 3D surface profile by surface matching of the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data in at least one stage of the registration, the registration being carried out with correct position and dimension," as recited in claim 12.

Accordingly, the combination of Packer and Rose also fails to render the limitations of claim 12 *prima facie* obvious. With respect to dependent claim 14, Applicants submit that claim 14 is dependent on independent claim 12, and independent claim 12 is shown to be patentable at least for the reasons given

above. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 14, at least by virtue of its dependency from claim 12. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

C. Rejection of Claim 4 under 35 U.S.C. § 103(a) is Erroneous

The Examiner takes the position that claim 4 is unpatentable over Packer in view of Rose and further in view of "A System for Multimodality Image Fusion" to Hemler *et al.* ("Hemler") and further in view of DE 19953308 to Williams *et al.* ("Williams"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

Hemler discloses a system for combining CT and MR images. Anatomical landmarks, such as bones, are segmented semi-automatically in both images, a transformation is determined and a registration measure is computed.

Williams discloses a registration method wherein fiducial markers [0037, 0038] are touched by a position sensor and the position of the markers with respect to the previously acquired image is ascertained by a computer in which the previously acquired image has been loaded. The touching of several markers enables image registration.

However, none of Hemler and Williams teach or fairly suggest the method of claim 4 comprising "**registering**, with the correct position and dimension, by **automatically correlating** in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and **refining the registration obtained in the first stage by the surface matching** in a later second stage." Namely, none of Packer, Hemler and Williams, alone or in combination, teach or fairly any <u>multi-stage process</u> as required by claim 4.

For the reasons given above, Packer also fails to teach or fairly suggest any "**registering**, with correct position and dimension, by **automatically correlating** in <u>a first stage</u> during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and **refining the registration obtained in the first stage by the surface matching** in <u>a later second stage</u>," as recited in claim 4. Particularly, Packer fails to teach or suggest any multi-stage operation.

For the reasons given above, Rose also fails to teach or suggest any <u>multi-stage operation</u> involving "**registering**, with correct position and dimension, by **automatically correlating** in <u>a first stage</u> during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and **refining the registration obtained in the first stage by the surface matching** in <u>a later second stage</u>," as recited in claim 4.

Accordingly, any combination of Packer, Rose, Hemler and Williams would fail to render the limitations of claim 4 *prima facie* obvious.

Furthermore, for at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to independent claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 4, at least by virtue of its dependency from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

D. <u>Rejection of Claims 13, 18 and 25-26 under 35 U.S.C. § 103(a) is Erroneous</u>

The Examiner takes the position that claims 13, 18 and 25-26 are unpatentable over Packer in view of Rose, further in view of Hemler and Williams.

Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer, Rose, Hemler and Williams are also applicable to this rejection. Particularly, none of Packer, Rose, Hemler and Williams in any combination render "the registration module **automatically correlates in a multi-stage process**, and the registration module registers, with the correct position and dimension, by **automatically correlating in a first stage** during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and refines the registration obtained in the **first stage by surface matching in a later second stage**," as recited in claim 13. (Emphases Added). Namely, none of Packer, Hemler and Williams, alone or in combination, teach or fairly any multi-stage process as required by claim 4.

Particularly, Hemler discloses a system for combining CT and MR images. Anatomical landmarks, such as bones, are segmented semi-automatically in both images, a transformation is determined and a registration measure is computed.

Williams discloses a registration method wherein fiducial markers [0037, 0038] are touched by a position sensor and the position of the markers with respect to the previously acquired image is ascertained by a computer in which the previously acquired image has been loaded. The touching of several markers enables image registration.

However, none of Hemler and Williams teach or fairly suggest the method of claim 13 wherein "the registration module **automatically correlates in a multi-stage process**, and the registration module registers, with the correct position and dimension, by **automatically correlating in a first stage** during the performance of the catheter application using at least one of distinct anatomical points and

artificial markers and refines the registration obtained in the **first stage by surface matching in a later second stage.**" (Emphases Added)

For the reasons given above, Packer also fails to teach or fairly suggest any "**registering**, with correct position and dimension, by **automatically correlating** in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and **refining the registration obtained in the first stage by the surface matching** in a later second stage," as recited in claim 4. Particularly, Packer fails to teach or suggest any multi-stage operation.

For the reasons given above, Rose also fails to teach or suggest any multi-stage operation involving "**registering**, with correct position and dimension, by **automatically correlating** in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and **refining the registration obtained in the first stage by the surface matching** in a later second stage," as recited in claim 4.

Accordingly, for reasons somewhat similar to claim 4, any combination of Packer, Rose, Hemler and Williams would fail to render the limitations of claim 13, and the somewhat similar features of claims 25-26 *prima facie* obvious.

Furthermore, for at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to independent claims 12, 19 and 22. Consequently, a *prima facie* case of obviousness cannot be established with regard to claims 13, 18 and 25-26, at least by virtue of their dependency from one of claims 12, 19 and 22. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

E. <u>Rejection of Claims 10-11 and 17 under 35 U.S.C. § 103(a) is Erroneous</u>

The Examiner takes the position that claims 9 and 15 are unpatentable over Packer in view of Rose and further in view of US 2003/0018251 to Solomon et al. ("Solomon"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer and Rose are also applicable to this rejection. Furthermore, the additional teachings of Solomon fail to remedy the deficiencies of Packer and Rose.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claims 10-11 and 17, at least by virtue of their dependency from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

F. <u>Rejection of Claims 15-16 under 35 U.S.C. § 103(a) is Erroneous</u>

The Examiner takes the position that claims 15-16 are unpatentable over Packer in view of Rose and further in view of Solomon. Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer and Rose are also applicable to this rejection. The additional teachings of Solomon fail to remedy the deficiencies of Packer and Rose.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claim 12. Consequently, a *prima facie* case of obviousness cannot be established with regard to claims 15-16, at least by virtue of their dependency from claim 12. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

G. Rejection of Claim 6 under 35 U.S.C. § 103(a) is Erroneous

The Examiner takes the position that claim 6 is unpatentable over Packer in view of Rose and further in view of US 2002/0087329 to Massaro ("Massaro"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer and Rose are also applicable to this rejection. The additional teachings of Massaro fail to remedy the deficiencies of Packer and Rose.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 6, at least by virtue of its dependency from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

H. Rejection of Claim 7 under 35 U.S.C. § 103(a) is Erroneous

The Examiner takes the position that claim 7 is unpatentable over Packer in view of Rose, in view of US 6,572,476 to Shoji et al. ("Shoji") and further in view of US 2004/0233217 to Chiu et al. ("Chiu"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer and Rose are also applicable to this rejection. The additional teachings of Shoji and Chiu fail to remedy the deficiencies of Packer and Rose.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 7, at least by virtue of its dependency

from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

Conclusion

For at least the reasons above, unpatentability cannot be established with regard to claims 1-26. Accordingly, Appellants respectfully request the Board to reverse all of the Examiner's rejections.

If the USPTO believes that personal communication will further the prosecution of this application, the Office is invited to contact the undersigned at the telephone number below.

The Commissioner is authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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VIII. 37 C.F.R. § 41.37(c)(1)(viii) – CLAIMS APPENDIX

1. (Previously Presented) A method of visually supporting an electrophysiology catheter application in the heart, comprising:

visualizing electroanatomical 3D mapping data, provided during the performance of the catheter application, of an area of the heart to be treated;

recording 3D image data of the area to be treated with a method of tomographical 3D imaging before the catheter application is carried out;

extracting a 3D surface profile of objects in the area to be treated from the 3D image data by segmentation; and

visualizing the electroanatomical 3D mapping data and 3D image data representing at least the 3D surface profile, the visualized electroanatomical 3D mapping data and 3D image data representing at least the 3D surface profile being registered, with correct position and dimension, by automatically correlating the electroanatomical 3D mapping data and 3D image data representing the 3D surface profile by surface matching, in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data.

2. (Previously Presented) The method as claimed in claim 1, wherein the 3D image data of the area to be treated are recorded with a method of at least one of X-ray computer tomography and magnetic resonance tomography.

3. (Previously Presented) The method as claimed in claim 1, wherein the 3D image data of the area to be treated are recorded by use of a 3D ultrasonic method.

4. (Previously Presented) The method as claimed in claim 1, wherein registering, with the correct position and dimension, by automatically correlating in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and refining the registration obtained in the first stage by the surface matching in a later second stage.

5. (Previously Presented) The method as claimed in claim 1, wherein the 3D image data are visualized via a volume rendering technique.

6. (Previously Presented) The method as claimed in claim 1, wherein the 3D surface profile from the 3D image data is visualized as polygonal grid.

7. (Previously Presented) The method as claimed in claim 1, wherein the superimposition is effected with adjustable transparency and adjustable blending factor.

8. (Previously Presented) The method as claimed in claim 1, wherein a registration is effected between a catheter used during the catheter application and the 3D image data and at least a part of the catheter is visualized in real time in the representation of the 3D image data representing at least the 3D surface profile.

9. (Original) The method as claimed in claim 8, wherein the at least one part of the catheter is visualized without superimposition of the 3D mapping data from time to time.

10. (Previously Presented) The method as claimed in claim 8, wherein, in each case, an instantaneous distance of a tip of the catheter from a predeterminable picture element of the 3D image data is calculated and the distance is represented coded in the visualization.

11. (Original) The method as claimed in claim 10, wherein the distance is represented by color coding of the visualization of the catheter.

12. (Previously Presented) A device, comprising:

at least one input interface for electroanatomical 3D mapping data and 3D image data;

a segmentation module constructed for segmenting the 3D image data in order to extract a 3D surface profile of objects contained within a volume recorded by way of the 3D image data;

a registration module connected to the segmentation module, the registration module configured to automatically correlate the electroanatomical 3D mapping data and the 3D image data representing the 3D surface profile by surface matching of the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data in at least one stage of the registration, the registration being carried out with correct position and dimension; and

a visualization module connected to the registration module, to superimpose the 3D mapping data and at least the 3D image data representing the 3D surface profile on one another in the correct position with the correct dimension and provide these for visualization via a display device.

13. (Previously Presented) The device as claimed in claim 12, wherein

the registration module automatically correlates in a multi-stage process, and

the registration module registers, with the correct position and dimension, by automatically correlating in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and refines the registration obtained in the first stage by surface matching in a later second stage.

14. (Previously Presented) The device as claimed in claim 12, wherein the visualization module is constructed for a real time visualization of a part of a catheter that is used within a representation of the 3D image data that forms at least the 3D surface profile.

15. (Previously Presented) The device as claimed in claim 14, further comprising a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data, the visualization module being constructed for the coded representation of the calculated distance in real time.

16. (Previously Presented) The device as claimed in claim 15, wherein the visualization module is constructed for colored visualization of the part of the catheter, the color varying in dependence on the distance calculated.

17. (Previously Presented) The method as claimed in claim 9, wherein, in each case, an instantaneous distance of a tip of the catheter from a predeterminable

picture element of the 3D image data is calculated and the distance is represented coded in the visualization.

18. (Previously Presented) The device as claimed in claim 13, wherein the visualization module is constructed for visualizing a part of a catheter used within a representation of the 3D image data, forming at least the 3D surface profile, in real time.

19. (Previously Presented) A method of visually supporting an electrophysiology catheter application in the heart, comprising:

recording 3D image data of an area of the heart to be treated with a method of tomographical 3D imaging, before electroanatomical 3D mapping data is provided during the performance of the catheter application;

extracting a 3D surface profile of objects in the area to be treated from the 3D image data by segmentation;

registering, with correct position and dimension, by automatically correlating the electroanatomical 3D mapping data and 3D image data representing the 3D surface profile by surface matching, in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data; and

displaying 3D mapping data and the 3D image data representing the 3D surface profile superimposed on one another in correct dimension and position.

20. (Previously Presented) The method as claimed in claim 19, wherein the 3D image data of the area to be treated are recorded with a method of at least one of X-ray computer tomography and magnetic resonance tomography.

21. (Previously Presented) The method as claimed in claim 19, wherein the 3D image data of the area to be treated are recorded by use of a 3D ultrasonic method.

22. (Previously Presented) A device for visually supporting an electrophysiology catheter application in the heart, comprising:

means for recording 3D image data of an area of the heart to be treated with a method of tomographical 3D imaging, before electroanatomical 3D mapping data is provided during the performance of the catheter application;

means for extracting a 3D surface profile of objects in the area to be treated from the 3D image data by segmentation; and

means for displaying the electroanatomical 3D mapping data and 3D image data representing at least the 3D surface profile superimposed on one another,

the electroanatomical 3D mapping data and 3D image data representing the 3D surface profile being registered by a registration means, with correct position and dimension, and by automatically correlating, by surface matching in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data.

23. (Previously Presented) The device as claimed in claim 22, wherein the 3D image data of the area to be treated are recorded with at least one of X-ray computer tomography and magnetic resonance tomography.

24. (Previously Presented) The device as claimed in claim 22, wherein the 3D image data of the area to be treated are recorded using 3D ultrasound.

25. (Previously Presented) The method of claim 19, further comprising:

registering, with the correct position and dimension, by automatically correlating in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and refining the registration obtained in the first stage by the surface matching in a later second stage.

26. (Previously Presented) The device of claim 22, wherein

the registration means automatically correlates in a multi-stage process, and

the registration means registers, with the correct position and dimension, by automatically correlating in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and refines the registration obtained in the first stage by surface matching in a later second stage.

IX. 37 C.F.R. § 41.37(c)(1)(ix) – EVIDENCE APPENDIX

None.

X. 37 C.F.R. § 41.37(c)(1)(x) – RELATED PROCEEDINGS APPENDIX

None.